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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,206	06/13/2000	RONG FU WANG	2026-4269US1	1577

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/529,206	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> David J Blanchard	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,5-8,10,12-15,26,28,29,67-77,83-85 and 87-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5-8,10,12-15,26,28,29,67-77,83-85 and 87-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/2004 has been entered.
2. Claims 1-2, 4, 9, 11, 16-25, 27, 30-66 and 86 have been cancelled.  
Claims 3, 5-8, 10, 12-15, 26, 28 and 67-77 have been amended.  
Claims 87-103 have been added.
3. Claims 3, 5-8, 10, 12-15, 26, 28-29, 67-77, 83-85 and 87-103 are pending and under examination.
4. This Office Action contains New Grounds of Rejections.

#### ***Rejections Withdrawn***

5. The rejection of claims 3, 5-8, 26, 28-29 and 67-86 under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed is withdrawn in view of the amendments to the claims.

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6. The rejection of claims 3, 5-8, 26 and 27 under 35 U.S.C. 102(a) as being anticipated by Chen et al is withdrawn in view of the amendments to the claims.

### ***Response to Arguments***

7. The response filed 4/8/2004 addresses the restriction requirement and argues that all the pending claims read on cancer peptides relating to the elected species of SEQ ID NO:4 and that certain claims should not be withdrawn because the claims are drawn to the same subject matter as other claims remaining in prosecution. This is found persuasive, however, in view of cancelled claims and there being no allowable generic claim, the claims will only be examined to the extent that they read on the cancer peptide of SEQ ID NO:4 and fragments thereof (i.e., SEQ ID NOS:14, 15, 26, 39, and 45) or derivatives thereof (i.e., SEQ ID NOS: 34-38 and 41).

### ***New Grounds of Rejection***

#### ***Claim Objections***

8. Claim 87 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 87 depends from base claim 3, which recites "An isolated cancer peptide consisting of about 10 contiguous amino

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acids...". Claim 87 recites "wherein the cancer peptide is about 10 amino acids in length", which does not further limit base claim 3.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3, 5-8, 10, 12-15, 26, 67-77 and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 3, 5-8, 10, 12-15, 26, 67-77 and 87 are indefinite for reciting "optionally" in claim 3. Do the cancer peptides contain additional amino acids at the N-terminus or not?

b. Claims 3, 5-8, 10, 12-15, 26, 67-77 and 87 are indefinite for reciting "functionally equivalent variants" in claim 3. The specification at page 13 loosely defines that phrase "functionally equivalent variants" include peptides with partial sequence homology, peptides having one or more specific conservative and/or non-conservative amino acid changes, peptide conjugates, chimeric proteins, fusion proteins and peptide nucleic acids. Thus, the phrase "functionally equivalent variants" encompasses peptides having disparate functions and the specification does not provide a standard for ascertaining the direction, requisite degree or endpoint, of the

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changes to the cancer peptides and one of ordinary skill in the art would not reasonably be apprised of the metes and bounds of the invention.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 3, 5-8, 10, 12-15, 26, 67-77 and 87 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

The claims are drawn to functionally equivalent variants having at least 85% sequence homology with the cancer peptides consisting of about 10 contiguous amino acids of SEQ ID NO:4 that include amino acids 55-62 or 127-136, but the specification does not disclose any homologous cancer peptides. The specification at page 9, lines 26-27, discloses that mammalian homologs are encompassed by the instant invention, including primate and murine homologs. Homologous cancer peptides (i.e., those having at least 85% sequence homology) can be broadly interpreted to being naturally occurring alleles. The general knowledge in the art concerning variants does not provide any indication of how the structure of one variant is representative of unknown

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variants. Reiger et al. (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. The skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Likewise, the specification does not describe the structural or functional aspects of these terms. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

13. Claims 3, 5-8, 10, 12-15, 26, 67-77 and 87-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The amendments to the claims filed 4/8/2004 have introduced NEW MATTER into the claims. The claims are interpreted as drawn to specific peptide residues of instantly claimed SEQ ID NO:4, wherein the specific peptide residues may optionally comprise 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 as well as

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functional variants thereof, wherein the functional variants have at least 85% sequence homology with the specific peptide residues of SEQ ID NO:4.

The specification as filed discloses that the cancer peptide of the instant invention "comprises" SEQ ID NO:4 and cancer epitopes, fragments or derivatives thereof as well as cancer peptides or portions thereof that share 85% sequence homology with SEQ ID NO:4 (i.e., the full-length) (see page 9, lines 10-20). The specification discloses that the cancer peptide of the present invention "comprises" amino acid residues 54-62 (SEQ ID NO:14), 53-62 (SE ID NO:25), 48-62 (SEQ ID NO:26), 43-62 (SEQ ID NO:43) and 127-136 (SEQ ID NO:15) (see pages 10-11). The specification does not disclose the narrower scope that the cancer peptide of the present invention 'consists' of amino acid residues 54-62 (SEQ ID NO:14), 53-62 (SE ID NO:25), 48-62 (SEQ ID NO:26), 43-62 (SEQ ID NO:43) and 127-136 (SEQ ID NO:15) as instantly claimed. While it appears that certain claimed species of SEQ ID NO:4 are disclosed in Tables 6 and 7, there is insufficient written support for the broader instant claim language, which is drawn not only to the cancer peptides of Tables 6-7, but also to isolated cancer peptides that have at least 85% sequence homology with the instantly claimed cancer peptides (i.e., residues 55-62 and 127-136 of SEQ ID NO:4 as well as amino acids 43-, 48-, 49-, 50-, 51-, 52-, 53- and 54-62 of SEQ ID NO:4). Additionally, the disclosure at page 9 appears to only have contemplated variants having at least 85% sequence homology relative to the full-length cancer peptide of SEQ ID NO:4 (i.e., cancer peptide comprising SEQ ID NO:4) and not 85% sequence homology to the instantly claimed amino acid residues instantly claimed. Table 7 at page 50 does not



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appear to provide adequate written description for the limitation that the cancer peptide includes amino acids 55-62 of SEQ ID NO:4 (i.e., SEQ ID NO:31 of Table 7). Although Table 7 at page 50 discloses a peptide consisting of amino acids 55-62 of SEQ ID NO:4 (SEQ ID NO:31), the data presented in Table 7 would not lead the skilled artisan to select this particular peptide over any of the other peptides in Table 7 and Applicant has not pointed to the specification where support for this particular cancer peptide can be found. Similarly, the data presented in Table 7 would not lead the skilled artisan to select the cancer peptide consisting of amino acids 54-62 (SEQ ID NO:33) and adequate written description for cancer peptides consisting of amino acids 43-62, 48-62, 55-62 (claim 88) and 54-62 (claim 88) of SEQ ID NO:4 cannot be found in Table 7 or in the specification as-filed. The specification does not provide adequate written description for functionally equivalent variants having at least 85% sequence homology with amino acids 127-136 of SEQ ID NO:4. Applicant has only disclosed the peptide consisting of amino acids 127-136 of SEQ ID NO:4 (SEQ ID NO:15; page 11) and has not disclosed said peptide optionally containing 1 to about 10 or 1 to about 5 additional contiguous amino acids at the N-terminus. The specification at page 11 discloses peptides having 1 to about 10 and 1 to about 5 additional amino acids (not necessarily contiguous) at the N-terminus of SEQ ID NOS:14, 25, 34-38 and 41-42 and not SEQ ID NO:15. Further, the instant claims are drawn to contiguous additional amino acids at the N-terminus, whereas the specification appears to only disclose that any additional amino acids at the N-terminus, a much broader scope than instantly claimed.

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Applicant's reliance on a generic disclosure and a limited number of species does not provide sufficient direction and guidance to the currently claimed limitations. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. Also, see MPEP 2163.05 Changes to the scope of Claims.

It is noted that entitlement to a filing date does not extend to subject matter, which is not disclosed, but would be obvious over what is expressly disclosed.

Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the instant claims which did not appear in the specification, as filed, represent a departure from the originally filed specification and claims, and introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action or specifically point out in the originally filed specification and claims where support for all of the instant claim limitations can be found.

14. Claims 3, 5-8, 10, 12-15, 26, 28-29, 67-77, 83-85, and 87-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such

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a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated cancer peptide consisting of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 55-62 of SEQ ID NO:4 or amino acids 127-136 of SEQ ID NO:4 and optionally 1 to about 10 or 1 to about 5 (claim 12) additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of the cancer peptide or a functional variant thereof, wherein said functional variant has at least 85% sequence homology with the cancer peptide, wherein said cancer peptide or functional variant is immunologically recognized by antigen specific cytotoxic T lymphocytes (CTLs) that are MHC I restricted, wherein the MHC I molecule is selected from HLA-A31, HLA-A3, HLA-A11, HLA-A33 and HLA-A68 and an immunogen comprising one or more of the above isolated cancer peptides (claims 28-29 and 83-85). The claims are also drawn to cancer peptides consisting of amino acids 43-, 48-, 49-, 50-, 51-, 52-, 53- and 54-62 of SEQ ID NO:4, wherein amino acid residue 54 of the cancer peptide consisting of amino acids 53-62 is substituted with threonine, alanine, isoleucine, valine, or leucine and the cancer peptide consisting of amino acids 54-62 has an additional valine or threonine at the N-terminus.

The specification teaches that certain synthetic peptides from the NY ESO-1/CAG-3 tumor antigen (i.e., SEQ ID NOS: 14, 15 and 25) as well as certain variant peptides of SEQ ID NO:25 (i.e., SEQ ID NOS:26-30, 34-38, and 41-42; Table 7) in combination with HLA-A31 are capable of being recognized by a specific CTL clone,

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CTL Clone 5, wherein said CTL clone released GM-CSF and was shown to lyse HLA-A31-positive tumor 586mel, but not the HLA-A31-negative and NY-ESO-1-positive tumor 397mel (see Figure 5, Tables 6-7 and Example 11). The specification only teaches certain claimed species of SEQ ID NO:4 in combination with HLA-A31 and not any other MHC class I molecule that can be recognized by CTLs. However, the specification does not teach just any functional equivalent variant cancer peptide having at least 85% sequence homology with a cancer peptide consisting of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 55-62 of SEQ ID NO:4 or amino acids 127-136 of SEQ ID NO:4 and optionally 1 to about 10 or 1 to about 5 additional contiguous amino acids of SEQ ID NO:4 or functional variants having at least 85% sequence homology with the cancer peptides consisting of amino acids 43-, 48-, 49-, 50-, 51-, 52-, 53- and 54-62 of SEQ ID NO:4 in combination with any MHC class I molecule, wherein the cancer peptide can be used to stimulate antigen specific T lymphocytes. Additionally, the specification does not teach a cancer peptide consisting of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 55-62 of SEQ ID NO:4 or amino acids 127-136 of SEQ ID NO:4 and optionally 1 to about 10 or 1 to about 5 additional contiguous amino acids of SEQ ID NO:4 or cancer peptides consisting of amino acids 43-, 48-, 49-, 50-, 51-, 52-, 53- and 54-62 of SEQ ID NO:4 in combination with HLA-A3, HLA-A11, HLA-A33 and HLA-A68, wherein the cancer peptide can be used to stimulate antigen specific T lymphocytes. It is not clear if CTLs could be generated using cancer peptides having at least 85% sequence homology with the instantly claimed cancer peptides of SEQ ID NO:4 in combination with an MHC

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class I molecule or using the instantly claimed cancer peptides of SEQ ID NO:4 in combination with HLA-A3, HLA-A11, HLA-A33 and HLA-A68. Further, the specification does not teach any cancer peptide consisting of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 127-136 of SEQ ID NO:4 that optionally includes 1 to about 10 or 1 to about 5 (claim 12) additional contiguous amino acids of SEQ ID NO:4 or even functional variants thereof, wherein the functional variant has at least 85% sequence homology with said cancer peptide.

Riott et al (Immunology, Fourth Edition, 1996, Mosby, page 7.9-7.11) teach that T cells recognizes cell-bound antigen in association with MHC molecules. MHC class I and class II act as guidance systems for T cells. This is known as MHC restriction. Only a minority of peptide fragments from a protein antigen are able to bind particular MHC molecules. Different MHC molecules bind different sets of peptides. Riott et al specifically teach Fig. 7.22 and Fig. 7.23, and also page 7.10, right column that the peptide sizes of 12-15 residues are optimal for MHC molecule class I and certain amino acids at certain positions are critical for binding to MHC class I. These teachings indicate that many species for example, the species encompassed by the broad language of instant claim 3, would not work. This fact is evidenced in Tables 6 and 7 (see SEQ ID NOS: 6-13, 16-24, 14 (Table 7), 31-33, 39-40 and 43-44). Also, the cancer peptide of SEQ ID NO:14 is shown to stimulate GM-CSF release by CTL clone 5 in Table 6, however, the same cancer peptide (SEQ ID NO:14) did not stimulate GM-CSF release by CTL clone 5 in a separate assay using the same HLA-A31-positive cells.

Wang et al (U.S. Patent 5,840,839, 11/24/1998) teach at column 19 that finding a peptide that binds to a MHC molecules and stimulates immune response is not a trivial matter. The '839 patent at column 19, lines 53 to 67 teaches that the structure of a T cell epitope that stimulates an immune response in context of MHC molecules is unpredictable in the current state of art. The '839 patent at columns 19-20, and Table 1 teaches that the various candidate T cell epitopes selected based on theoretical binding motif of one class of MHC molecule, i.e. HLA-A31 do not work when they are experimentally tested as shown in Table 1. This suggests that theoretically selected T cell binding motifs have to be tested experimentally in order to determine whether they are actually T cell epitopes or not. While it is known that size is a factor in processing and recognition of an epitope, it is also known that other factors are involved in T cell stimulation, all of which have not been elucidated. For support, see Bixler et al (U.S. patent 5,785,973, column 5, line 47 to column 7, line 59). The art of Geysen (U.S. Patent 5,539,084) shows that even for peptides of similar size derived from the same "parent" polypeptide, not all will be capable of interacting with T-cells (column 2, lines 5-9 and Figure 6), thus demonstrating the degree of uncertainty in the art for predicting which subsets or portions of a larger polypeptide will be capable of interacting with or stimulating T-cells. Neither the specification nor the prior art teach the full-scope of cancer peptides of SEQ ID NO:4 instantly claimed or functionally equivalent variants having at least 85% sequence homology with the instantly claimed cancer peptides of SEQ ID NO:4 that are immunologically recognized by antigen specific cytotoxic T lymphocytes.

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One cannot extrapolate the teachings of the specification, which are limited to certain cancer peptide species of SEQ ID NO:4 in combination with HLA-A31 to the instant invention, because there is insufficient guidance or exemplification of any correlation between functional variant cancer peptides having at least 85% sequence homology with the a cancer peptide consisting of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 55-62 of SEQ ID NO:4 or amino acids 127-136 of SEQ ID NO:4 and optionally 1 to about 10 or 1 to about 5 additional contiguous amino acids of SEQ ID NO:4 or cancer peptides consisting of amino acids 43-, 48-, 49-, 50-, 51-, 52-, 53- and 54-62 of SEQ ID NO:4 capable of specifically activating cytotoxic T lymphocytes with the claimed specificity/activity. The specification however does not disclose common structural attributes that identify the claimed cancer peptides or functionally equivalent variants thereof. There is insufficient guidance regarding the parameters and specific cancer peptide sequences, which correlate with the ability to stimulate T cell with any MHC molecule and generate CTLs with the claimed specificity/activity commensurate in scope with the claims. There is insufficient guidance regarding selection of peptides that meet the instant criteria of stimulating T lymphocytes with specific activity. Further, although SEQ ID NO:4 and select cancer peptides of SEQ ID NO:4 presented in Tables 6 and 7, when pulsed to HLA-A31-positive tumor cell lines could be recognized by CTL clone 5, the vast majority of variants in Table 6 as well as several cancer peptides in Table 7 do not stimulate CTLs. Thus, there is insufficient guidance regarding the parameters and sequences of peptides which correlate with the ability to be recognized by the specific CTL clone, CTL clone 5.

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The specification provides insufficient guidance with regard to these issues and provides no working examples with a cancer peptide of the instant invention that would work or would work with any MHC molecule other than HLA-A31. Considering the state of art, the broad scope of claims in respect to the nature of the peptide and also to the nature of MHC molecules, and insufficient guidance with respect to the broadly claimed variants and cancer peptides longer than 10 amino acids, it is concluded that that undue experimentation would be required to practice the claimed invention.

Limiting the scope to the positive (i.e., stimulate GM-CSF release; Tables 6-7) T cell reactive cancer peptides (listed in claims 10, 13, 69, 72 and 74-77), and also limiting scope of the MHC molecule to HLA-A31 MHC class I molecule would obviate this rejection.

***Claim Rejections - 35 USC § 102***

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

16. Claims 28-29 and 83-85 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen et al (Proc. Natl. Acad. Sci USA, 94:1914-1918, March 1997, cited PTO-892 dated 7/30/2002).



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The claims are drawn to an immunogen comprising one or more of the isolated cancer peptides of claim 3 alone or in combination with an MHC molecule selected from the group consisting of HLA-A31, HLA-A3, HLA-A11, HLA-A33 and HLA-A68, wherein the immunogen illicitly an immune response by an antigen specific T lymphocyte.

Chen et al teach an immunogenic antigen (NY-ESO-1; Figure 3), which is aberrantly expressed in human cancers and detected by either cytotoxic T cells or antibodies. The immunogenic antigen taught by Chen et al consists of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 55-62 of SEQ ID NO:4 or amino acids 127-136 of SEQ ID NO:4 and optionally 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus of the immunogenic antigen or a functional variant thereof, wherein said functional variant has at least 85% sequence homology with the immunogenic antigen (see Figure 3). For this rejection, the term "comprising" is interpreted as open language meaning that the immunogen consists of about 10 contiguous amino acids of SEQ ID NO:4 that includes amino acids 55-62 of SEQ ID NO:4 or amino acids 127-136 of SEQ ID NO:4 and optionally 1 to about 10 additional contiguous amino acids of SEQ ID NO:4 at the N-terminus as well as additional amino acids at the N- and C-termini and thus, the claims read on the full-length NY-ESO sequence of Chen et al.

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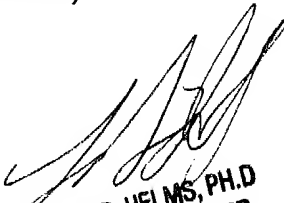
*Conclusion*

17. No claim is allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,  
David J. Blanchard  
571-272-0827

  
LARRY R. HELMS, PH.D  
PRIMARY EXAMINER